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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,657	11/28/2001	Sophie E. V. Martin	56297-5016-01	8313

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WASHINGTON, DC 20004

EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637

13

DATE MAILED: 08/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/994,657

Applicant(s)
Martin et al.

Examiner
Joyce Tung

Art Unit
1637



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 27, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11 6) ☐ Other:

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DETAILED ACTION

The amendment filed 6/27/2003 has been entered. Following the entry of the amendment, claims 1-11 are pending.

1. The rejections of claims 12 under 35 U.S.C. § 112 second paragraph and under 35 U.S.C. 103(a) as being unpatentable over Dower. (5,186,800) are withdrawn.
2. The rejection of claims 1-8 under 35 U.S.C. 112, first paragraph is withdrawn.

Information Disclosure Statement

- 3.. The references, TR and UR, lined through were not considered because there are no translations for the references.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dower. (5,186,800).

Dower disclosed the method of the present invention is used to collect intracellular substances released from cells (See column 5, lines 21-25). The method is effective with wide variety of prokaryotic cells including both gram-positive and gram-negative bacterial cells (See column 4, lines 9-57). Dower discussed how the electrical conductivity of the medium or solution and the cell density are affecting on the electrical field (See column 4, lines 58-68 to column 5, lines 1-20). Conveniently, a non-conductive medium, such as water or sucrose is used for suspending the cells (See column 5, lines 19-20). Dower also disclosed that interelectrode spacing is critical in that it determines the electric field strength to which sample is exposed. (See column 6, lines 50-59). Usually, the electrode space is below 2.5 mm, preferably being in the range from 1.0mm to 2.0 mm (See column 6, lines 47-50). Dower further discussed the reasons to choose a precise electric field strength based upon the cellular dimensions, for example, smaller size bacterial, the voltage 10-15kV/cm is applied and larger size bacterial, the voltage 5 to 10 kV/cm is applied (See column 7, lines 44-52). Moreover, Dower discussed the duration applied cross the electrodes to promote the permeability of the cell wall. The precise voltage and pulse duration selected is depend on the nature of prokaryotic cell being treated. The pulse duration is generally be in the range from 2-20 sec or longer being in range from 3 to 10

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sec (See column 8, lines 10-37). Finally, Dower indicates that the type of pulse waveform provided by the pulse generator is not critical (See column 7, lines 53-57).

Dower does not disclose applying the voltage not more than 50 volts including the range of the voltage between 0.5-50 volts, and the period for applying voltage is at least 30 seconds or 2 minutes continuously.

However, based upon the discussion of the factors which affects the permeability of the bacterial cells in the teachings of Dower it would have been prima facie obvious for one of ordinary skill in the art at the time of the instant invention to apply the electroporation of Dower to release intracellular material from bacterial cells with the optimization of the amount of volts, and the time needed for the pulse. The motivation to vary the voltage is to avoid the denaturation of intracellular material. The electric conductivity of the medium or suspension and the duration of the electrical field as discussed by Dower would have been taken into consideration by one of ordinary skilled in the art at the time of the instant invention to release intracellular material from cells by applying a continuous voltage of not more than 50 volts to a suspension. Thus it would have been prima facie obvious to apply a continuous voltage not more than 50 volts to release intracellular material from cells in a cellular suspension.

The response argues that Dower does not teach the limitations presented in the claims. However, the motivation to apply the continuous voltage not more than 50 volts including the range of the voltage between 0.5-50 volts and the period for applying the voltage, at least 30

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seconds or 2 minutes continuously is set forth in the Office action mailed 3/27/2003 (See the above paragraph). Thus, the rejection is maintained.

NEW GROUNDS OF REJECTIONS NECESSITATED BY THE AMENDMENT

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-11 are vague and indefinite because of the phrase a "continuous" voltage. Since any voltage with a given duration is always continuous it is unclear whether or not there is special meaning for the term. Any amount of voltage used in releasing intracellular material from cells must have a duration. Clarification is required.

Summary

8. No claims are allowable.

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9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

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9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

J. T

August 13, 2003

Jeffrey Siew
JEFFREY SIEW
PRIMARY EXAMINER

8/20/03